

Applicants: Robert J. Winchester, et al.  
U.S. Serial No.: 09/500,746  
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#### **REMARKS**

Claims 18 and 19 are pending and under examination. Applicants have amended claim 18 herein. Applicants maintain that this amendment raises no issue of new matter, and respectfully request entry of this Amendment. Upon entry of this Amendment, claims 18 and 19 will still be pending and under examination.

In view of the arguments set forth below, applicants maintain that the Examiner's rejections made in the May 5, 2003 Final Office Action have been overcome, and respectfully request that the Examiner reconsider and withdraw same.

#### **The Claimed Invention**

This invention provides a composition comprising (a) an amount of a bicyclam capable of inhibiting the activation of the CXCR4 receptor by SDF-1, and (b) a pharmaceutically acceptable carrier, wherein the composition is indicated for treating rheumatoid arthritis.

#### **Rejection Under 35 U.S.C. §102(a)**

The Examiner rejected claims 18 and 19 under 35 U.S.C. §102(a) as allegedly anticipated by Schols, et al. (Antiviral Research 35, 147-156, 1997).

In response to the Examiner's rejection, applicants respectfully traverse.

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As stated above, claims 18 and 19 provide a composition comprising (a) an amount of a bicyclam capable of inhibiting the activation of the CXCR4 receptor by SDF-1, and (b) a pharmaceutically acceptable carrier, *wherein the composition is indicated for treating rheumatoid arthritis.*

To anticipate the instant composition, Schols, et al. would have to teach each and every element thereof. They fail to do this.

Schols, et al. teach that the bicyclam AMD3100 interacts with the CXCR4 receptor and prevents both infection of CXCR4-positive cells with T-tropic HIV-1 and specific binding of CXCR4 receptor with an anti-CXCR4 monoclonal antibody (12G5).

Schols, et al. do not, however, teach a composition comprising (a) an amount of a bicyclam capable of inhibiting the activation of the CXCR4 receptor by SDF-1, and (b) a pharmaceutically acceptable carrier, *wherein the composition is indicated for treating rheumatoid arthritis.* Schols, et al. therefore fail to teach each and every element of the rejected claims.

In view of the above remarks, applicants maintain that claims 18 and 19 satisfy the requirements of 35 U.S.C. §102(a).

#### **Rejections Under 35 U.S.C. §102(b)**

The Examiner rejected claims 18 and 19 under 35 U.S.C. §102(b) as allegedly anticipated by De Vreese, et al. (Antiviral Research 29, 209-219, 1996) as evidenced by Schols, et al., and Datema, et al. (Antimicrobial Agents and Chemotherapy 40, 750-754, 1996) as

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evidenced by Schols, et al.

In response to the Examiner's rejections, applicants respectfully traverse.

Claims 18 and 19 are described above.

To anticipate the claimed composition, both De Vreese, et al. and Datema, et al. would have to teach each and every element thereof. They fail to do this.

De Vreese, et al. teach that bicyclams inhibit HIV-1 infection by interfering with virus-cell fusion (i.e., viral entry). Datema, et al. teach that the bicyclam compound JM3100 (i.e., AMD3100) inhibits HIV-1 infection *presumably* by blocking virus-cell fusion.

Neither De Vreese, et al. nor Datema, et al., however, teach a composition comprising (a) an amount of a bicyclam capable of inhibiting the activation of the CXCR4 receptor by SDF-1, and (b) a pharmaceutically acceptable carrier, *wherein the composition is indicated for treating rheumatoid arthritis*. De Vreese, et al. and Datema, et al. therefore each fail to teach each and every element of the rejected claims.

The Examiner also rejected claim 18 under 35 U.S.C. §102(b) as allegedly anticipated by Murrer, et al. (U.S. Patent No. 5,021,409).

In response to the Examiner's rejection, applicants respectfully traverse.

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Murrer, et al. teach that certain bicyclam compounds have potential in treating AIDS and other retroviral infections.

Murrer, et al. do not teach a composition comprising (a) an amount of a bicyclam capable of inhibiting the activation of the CXCR4 receptor by SDF-1, and (b) a pharmaceutically acceptable carrier, *wherein the composition is indicated for treating rheumatoid arthritis*. Murrer, et al. therefore fail to teach each and every element of the rejected claims.

In view of the above remarks, applicants maintain that claims 18 and 19 satisfy the requirements of 35 U.S.C. §102(b).

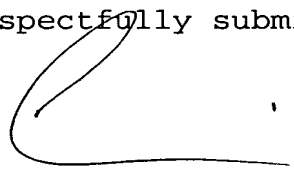
#### Summary

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

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No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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